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Registration Decision RD2014-14

Streptomyces acidiscabies strain RL-110^{T} and Thaxtomin A

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Registration Decision for *Streptomyces acidiscabies* strain RL-110^T and Thaxtomin A

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of MBI-005 TGAI and MBI-005 EP, containing the active ingredient *Streptomyces acidiscabies* strain RL-110^T and Thaxtomin A, for the partial suppression of dandelions on turf grass (Kentucky bluegrass and fescue turf).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-24, *Streptomyces acidiscabies strain RL-110^T and Thaxtomin A*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Streptomyces acidiscabies* strain RL-110^T and Thaxtomin A and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2013-24. This decision is consistent with the proposed registration decision stated in PRD2013-24.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2013-24, *Streptomyces acidiscabies strain RL-110^T and Thaxtomin A* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is MBI-005 EP and MBI-005 TGAI?

The technical grade active ingredient (TGAI), MBI-005 TGAI, and the end-use product (EP), MBI-005 EP, contain killed, non-viable *S. acidiscabies* strain RL-110^T and spent fermentation media as the active ingredient. During the fermentation process, *S. acidiscabies* strain RL-110^T produces a phytotoxin, Thaxtomin A, which is the basis for the mode of action of the active ingredient.

It is believed that Thaxtomin A produces phytotoxic effects through alterations in calcium and sodium ion transport in cells as well as inhibiting cellulose biosynthesis. The toxicity in plants is similar to the effects caused by known cellulose biosynthesis inhibitors, such as dichlobenil and isoxaben.

MBI-005 EP is a commercial herbicide that is to be used for the control of dandelions on Kentucky bluegrass and fescue turf.

Health Considerations

Can Approved Uses of *Streptomyces acidiscabies* strain RL-110^T and Thaxtomin A Affect Human Health?

S. acidiscabies strain RL-110^T and Thaxtomin A is unlikely to affect your health when MBI-005 EP is used according to the label directions.

People could be exposed to *S. acidiscabies* strain RL-110^T and Thaxtomin A when handling and applying MBI-005 EP. When assessing health risks, several key factors are considered:

The microorganism's biological properties (for example, production of toxic by-products); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When MBI-005 EP and *S. acidiscabies* strain RL-110^{T} were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease. Furthermore, *S. acidiscabies* strain RL-110^{T} is not viable in the end-use product.

Residues in Water and Food

Dietary risks from food and water are not of concern

S. acidiscabies are common bacteria found in agricultural soils of North America that cause plant disease. When MBI-005 EP was administered orally to rats, no signs of toxicity or disease were observed, and no metabolites of toxicological significance have been shown to be produced by this strain of *S. acidiscabies*.

The end-use product has not been approved for food uses, therefore, as no residues of MBI-005 EP are expected on agricultural commodities and the establishment of an MRL is not required for *S. acidiscabies* strain RL-110^{T} and Thaxtomin A. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling MBI-005 EP

Occupational risks are not of concern when MBI-005 EP is used according to label directions, which include protective measures

Workers handling MBI-005 EP can come into direct contact with *S. acidiscabies* strain RL-110^{T} and Thaxtomin A on the skin or by inhalation. For this reason, the product label will specify that workers exposed to the end-use product must wear waterproof gloves, long-sleeved shirts, long pants, a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When MBI-005 EP Is Introduced Into the Environment?

Environmental risks are not of concern.

S. acidiscabies is a bacterium that occurs naturally in soils. This bacterium is a plant pathogen that causes scab (i.e. cork-like lesions) on tuber crops. The microorganism's ability to infect plants is achieved through the production of a plant toxin called Thaxtomin A.

No environmental exposure to viable cells of *S. acidiscabies* strain RL-110^{T} are expected following the proposed use of MBI-005 EP because the bacterium is killed prior to formulation. Based on the proposed use of MBI-005 EP as a spot treatment for dandelions, environmental exposure to Thaxtomin A is expected to be minimal.

Studies were conducted to determine the effects of MBI-005 TGAI or MBI-005 EP on birds, fish, bees, terrestrial and aquatic arthropods, aquatic plants and algae. These studies showed that MBI-005 TGAI was not toxic to birds, fish, bees, or arthropods. As expected, MBI-005 EP was toxic to terrestrial and aquatic plants, and algae.

Although terrestrial non-arthropod invertebrate, and microorganism toxicity/pathogenicity testing were not assessed in the review, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected.

Value Considerations

What Is the Value of MBI-005 EP?

The registration of MBI-005 EP provides another non-conventional control option for dandelion in turf grass.

There are a number of conventional herbicides currently registered in Canada for the control of dandelion in turfgrass, including 2,4-D, dicamba, mecoprop-p, etc. However, there are fewer herbicides available to users in certain provinces and jurisdictions that have enacted legislation restricting pesticide availability for non-essential or cosmetic use. Corn gluten, chelated iron (FeHEDTA) and *Phoma macrostoma* strain 94-44B are non-conventional herbicides that are not included on the list of pesticides prohibited for sale by many provincial and municipal legislations. It is conceivable that MBI-005 EP could also be permitted for use in jurisdictions that have enacted legislation restricting pesticide availability, thereby providing a viable alternative in the control of dandelion in lawns.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MBI-005 EP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed to large quantities of MBI-005 EP, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since all microorganisms, including *S. acidiscabies* strain RL-110^T, contain substances that are potential sensitizers. Therefore, anyone handling or applying MBI-005 EP must wear appropriate waterproof gloves, a long-sleeved shirt, long pants, a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks. Also, the signal words, "POTENTIAL SENSITIZER" are required on the principal display panel of MBI-005 TGAI and MBI-005 EP; and the precautionary statements: "Avoid contact with eyes, skin and clothing.", "Avoid inhaling/breathing mists." and "May cause sensitization." are required on the secondary display panel of the label for MBI-005 EP.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of MBI-005 EP.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-24, *Streptomyces acidiscabies strain RL-110^T and Thaxtomin A*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.